

2016 APR -1 AM 8:37 UNRESTRICTED

2016 March 29

PERFORMANCE IMPROVEMENT & OVERSIGHT
Regulatory Affairs
145-CNNO-16-0011-L

Mr. Brian Torrie
Director General, Regulatory Policy Directorate
Canadian Nuclear Safety Commission
280 Slater Street
P.O. Box 1046, Station B
OTTAWA, Ontario K1P 5S9

1.01.02
FILE DOSSIER 1-8-8-0
REFERRED TO REFERÉ À Torrie, B.

Dear Mr. Torrie:

Canadian Nuclear Laboratories Comments on REGDOC 2.9.1: *Environmental Protection: Environmental Policy, Assessments and Protection Measures*

The purpose of this letter is to provide Canadian Nuclear Laboratories' (CNL) comments on draft REGDOC 2.9.1: *Environmental Protection, Environmental Policy, Assessments and Protection Measures*. The draft REGDOC represents the consolidation of two documents, both numbered REGDOC 2.9.1, one regarding environmental protection policies, programs and procedures, and the other regarding environmental assessment processes. We appreciate that with the merging of these two documents the Canadian Nuclear Safety Commission (CNSC) will have integrated all of the associated guidance. However, because REGDOC 2.9.1 is the consolidation of multiple documents, it will add complications in compliance with operating licences.

The REGDOC raises the following general questions and comments on the guidance provided (see Attachment A for the detailed comments):

- References to other Regulatory Documents and Standards – REGDOC 2.9.1 attempts to paraphrase several different regulatory documents (CSA and ISO standards, and REGDOCs), which has the potential to create some inconsistencies in the terminology and interpretation of the documents. These documents are also subject to periodic review, which has the potential to further compound the number of inconsistencies over time. This should be remedied by citing, rather than paraphrasing, the regulatory documents.
- The draft REGDOC refers to “environmental assessment (EA)” to be either under CEAA 2012 or NSCA. The distinction of an environmental assessment under the CEAA 2012 and an EA under the NSCA is not clear throughout the document. This may lead to confusion and uncertainty if environmental protection reviews under NSCA are also being called an EA. CNL suggests that the term EA should only be used when referencing the CEAA 2012, while

Canadian Nuclear Laboratories

Laboratoires Nucléaires Canadiens

Chalk River Laboratories
286 Plant Road
Chalk River, Ontario
Canada K0J 1J0
Telephone: 613-584-3311
Toll Free: 1-866-513-2325

Laboratoires de Chalk River
286, rue Plant
Chalk River (Ontario)
Canada K0J 1J0
Téléphone: 613-584-3311
Sans frais: 1-866-513-2325



an “EA under NSCA” should be called an “environmental protection assessment” (EPA) or some other term for clarity.

- While there is significant information about the process for an EA under CEAA, there is no information about the triggers or process for a Section 67 review under CEAA. This REGDOC refers the user to the operation policy statement for projects on federal lands. However this document does not provide the guidance on which projects the CNSC is required to conduct a review of in accordance with Section 67. CNL views this as a significant gap.
- Environmental Assessments (EAs) – CNL supports the federal government’s decision to make the CNSC the sole responsible authority for nuclear projects under the *Canadian Environmental Assessment Act, 2012* and the certainty that that provides. Given the newly elected government’s plans to carry out an “immediate review” of EA processes, we would like to further reinforce our support of the CNSC’s designation as responsible authority, and the need to grandfather any changes to the Act.
- Levels of Risk - We appreciate the recognition that there are varying levels of risk associated with nuclear facilities and activities. However, statements that “All licence applications are subject to an EA, commensurate with the scale and complexity of the environmental risks” do not entertain the possibility that no EA is required (i.e., no environmental interactions). Similarly, “for facilities with no interactions, the licensee’s ERA is considered to be complete with the characterization and the demonstration of no interaction,” but it is unclear how such a determination would be made, and for each level of risk.
- Transition from EA to ERA - Once an EA has been completed under CEAA, any follow-up monitoring would be captured under the CSA N288 series of standards (N288.4, N288.5, and N288.6) and the broader governance of CNL’s ISO 14001 Environmental Management System and associated Environmental Monitoring Program (EMP). The transition from EA follow-up to the ERA and other programs should be outlined in REGDOC 2.9.1. The rigour that an ERA provides (equivalent to that of an EA) should also be acknowledged.
- There is a recommendation to benchmark the monitoring program against top performing facilities. There is a need to clarify which facilities are considered top performing and according to whom (e.g., OPEX, WANO, INPO). Also, while some benchmarking data is available for nuclear facilities, limited environmental data are available from other facilities.
- This REGDOC does not provide any information on the release limits and how they will be defined. This was the expectation through numerous discussions with the CNSC on the discussion paper 12-02, *Process for Establishing Release Limits and Action Levels at Nuclear Facilities*. Since CNL’s Chalk River Laboratories is one of the only facilities with release limits



lower than 1 mSv, CNL would like to have the methodology for the selection of this release limit explained.

While it is not the central focus of the public review process, we would like to offer the following feedback on the Impact Statement that was developed for this REGDOC.

- Impact Statement - The argument that “the CNSC must give consideration to values and principles that are difficult to quantify in a dollar value” is not a satisfactory reason for not conducting a strict quantitative assessment of the costs and benefits associated with this REGDOC. Costs should be estimated and at the expense of the federal government, as is the practice when establishing new regulatory instruments in other jurisdictions.
- According to the Impact Statement, “the CNSC does not expect that significant additional information will be required from applicants or licensees, nor that significant additional cost will be incurred by the applicants or licensees.” It is not clear how this conclusion could have been reached without a quantitative assessment, or how this could change if changes are made to CEEA 2012 as a result of the pending federal review.

We strongly urge the CNSC to consult with its stakeholders to help amend the proposed REGDOC. CNL believes a workshop to gather and address stakeholder issues with this current draft of REGDOC 2.9.1 would benefit all involved. We welcome the opportunity to provide the CNSC with the remainder of our comments in such a forum.

If you have any questions regarding this submission, please contact me as below.

Yours sincerely,

S. Karivelil, Manager
Regulatory Affairs
Phone: 613-584-3311, ext. 48021
Email: solly.karivelil@cnl.ca

SK/mj
Attachment (1)

c	L. Ethier (CNSC)	Consultations (CNSC)		
	S.K. Cotnam	K. Daniels	G. Dolinar	S. Faught
	C. Gallagher	J.D. Garrick	K. Kehler	H. Khartabil
	W.S. Pilkington	J. Stone	R. Swartz	
	>CR CNSC Site Office	>CR Licensing	>SRC	



Attachment A
Canadian Nuclear Laboratory Comments on draft REGDOC-2.9.1,
Environmental Protection Environmental Policy, Assessments and Protection Measures

#	Document/ Excerpt of Section	Industry Issue	Suggested Change (if applicable)	Major Comment/ Request for Clarification ¹	Impact on Industry, if major comment
1.	Entire	<p>This regulatory document (REGDOC) references several CSA standards as part of its requirements. However, it also cites requirements and language that are different from the relevant CSA Standards. This may cause ambiguity and misinterpretation of its intent.</p> <p>The REGDOC 2.9.1 appears to incorporate CSA nuclear standards of environmental protection into a regulatory framework. Focus has changed entirely from previous version (EA focused) to a discussion of all licensing requirements, licensing basis, and all CSA standards (288.4, .5, and .6). This document has expanded and its role is now clearer. The concept of a “requirements” section followed by “guidance” section is good. However, rather than referencing the CSA standards the document often paraphrases the CSA expectations or expands beyond the expectations in the CSA standards. If the intent is to meet the standard, then just say so, and rely on the CSA document to provide the “requirements”.</p> <p>For example: Not all of the CSA N288 series of standards were incorporated or referenced. What is the thinking behind referencing some but not others?</p>	Simplify the document to use a direct reference to standards including CSA without additional clarifications which may create conflicting expectations. If there are sections of the CSA standards which are to be overridden by this REGDOC, these exceptions should be specifically listed.	Major Comment	Regulatory uncertainty may result in an unnecessary burden. Regulatory requirements may differ from Canadian standards and create conflicting expectations.



UNRESTRICTED

	Continuation of comment #1	<p>Definitions of “should, shall, may” differ from CSA standards. I.e. if a “should” is used, do we need to justify why we are not doing it.</p> <p>There is a risk that this document changes CSA “should” statements into “shall” statements</p> <p>CSA N288.8 on Action Levels is still in draft, but will also be relevant once it is approved.</p> <p>In Section 4, if required to follow 288.6, it is not necessary to provide any additional guidance and requirements.</p> <p>In Section 4, the definitions of emissions and effluents contradict a number of CSA standards. This would require major changes to all documents. Should keep the CSA definitions.</p> <p>In Section 4, bottom pg 13. Should state that licensees can use CSA N288.1 for Human Health Risk Assessment (HHRA).</p> <p>Section 4.2 is effectively a rehash of CSA 288.4 and .5</p> <p>Section 4.2.2 requires action levels for all pathways. However, the draft CSA N288.8 does not require action levels for all contaminants or monitored pathways.</p> <p>Section 4.2.2 references G-228. N288.8 should be available before this document is released so should update all reference to the new standard.</p> <p>Section 4.6 is a rehash of CAN/ISO 14001. Suggest simply listing the CSA standards to be adhered to, rather than “reinterpreting / restating” the CSA requirements. The guidance section (i.e. how CNSC interpret the standards) could stay.</p>			
--	----------------------------	--	--	--	--



2.		<p>Ministerial Statement - Government of Canada Moves to Restore Trust in Environmental Assessment, Wednesday, January 27, 2016 – “As stated in the Speech from the Throne, the Government will introduce new environmental assessment processes as part of our efforts to restore public trust. Public input will be sought and considered.</p> <p>Decisions will be informed by scientific evidence. Indigenous peoples will be more fully engaged in reviewing and monitoring major resource development projects. The process will have greater transparency.”</p> <p>Will this change REGDOC 2.9.1 at this point?</p>	<p>Suggest that any environmental assessments which follow this document would be grandfathered against future changes in CEAA requirements</p>	<p>Major Comment</p>	<p>Regulatory uncertainty</p>
3.	<p>General</p>	<p>It should be acknowledged that N288.6 does not apply to some of the licensees captured in this REGDOC. There is a potential gap in the standards and guidance available for the conduct of ERAs for Waste Nuclear Substance Licensees, Class II licensees, etc. that warrant an ERA.</p>	<p>Need clarification.</p>	<p><i>Clarification</i></p>	<p>Regulatory uncertainty.</p>
4.	<p>General</p>	<p>The proposed REGDOC indicates that “for facilities with no interactions, the licensee’s ERA is considered to be complete with the characterization and the demonstration of no interaction.” It is unclear how this determination would be made for ERAs and for each level of risk, or grade.</p>	<p>There is the suggestion that Screening Level Risk Assessments (and associated pathway determinations) would be appropriate for Class II facilities and facilities under the Nuclear Substances and Radiation Devices Regulations. This should be clarified.</p>	<p>Major Comment</p>	<p>Regulatory uncertainty.</p>
5.	<p>General</p>	<p>It is agreed that the licensee should “use the ERA to identify substances requiring an action level.” Action levels are only to be established for radiological parameters, in keeping with the original guidance (G-228).</p>	<p>Clarification.</p>	<p><i>Clarification</i></p>	<p>Ratcheting up of regulatory requirements.</p>



UNRESTRICTED

6.	General	As indicated, “every applicant or licensee must have an ERA, commensurate with the scale and complexity of the environmental risks associated with the facility or activity; the ERA is subject to regular updates (at least every five years, and whenever significant change occurs in either the facility or activity.” However, there is no clear guidance on what constitutes a “significant change” for each level of risk, or grade.	Need clarification on “significant change.” Also note that there is a need to manage the changes in a similar manner to the way in which it is done for the Safety Report (i.e. an analysis of record).	Major Comment	Administrative burden.
7.	General	It is unclear throughout the REGDOC the nature of the applications within the meaning of “licence applications” and to which the REGDOC applies. Verbally, CNSC staff have indicated that changes within the objective of the licensing basis are not captured by this REGDOC, presumably because they are not considered a “licence application”. If the REGDOC is revised to explicitly distinguish between applications that must go before the Commission and require the support of an EA (CEAA or under the NSCA) and Staff can make without an ERA, the document would be clearer.	Clarify that EAs under the NSCA are only required for licensing applications that require a commission decision	Major Comment	Regulatory uncertainty
8.	Preface, page i, para. 3	This states that the REGDOC will be used to assess licensing applications. It is unclear what applications or requests are within this definition.		<i>Clarification</i>	
9.	Preface, page i	Para. 3, bullet 2: a phase-in period should be included for facilities that do not have an ERA.		<i>Clarification</i>	
10.	Preface, page i	Para. 6: The detail described in this REGDOC would not normally be included in the generic licence conditions.		<i>Clarification</i>	
11.	Preface, page ii	Para. 1: There is no guidance on the nature of the “supportable evidence” needed to demonstrate a requirement has been fulfilled.	Provide guidance for nature of acceptable evidence after each REGDOC ‘requirements’ section	<i>Clarification</i>	



UNRESTRICTED

12.	Preface, S1, S 1.2	These sections are primarily limited to EA and ERA, but document also includes effluent monitoring, environmental monitoring and EMS.	Expand Preface, Introduction and Scope sections to include effluent monitoring, environmental monitoring and EMS.	Major Comment	Unclear scope increases risk of industry misapplying the REGDOC.
13.	Preface, 2 nd last paragraph	Guidance throughout the REGDOC is not true guidance, as the CNSC expects licensees to consider guidance and if they choose not to follow it they should explain how their chosen alternate approach meets “regulatory requirements”.	Remove this wording from the Preface.	Major Comment	It is confusing for licensees, the public and other stakeholders when licensees are expected to explain how their chosen alternate approach meets “regulatory requirements” that are set out in the “guidance”.
14.	Preface & Section 1.2 & Section 3 & throughout (5-CNL)	<p>“Every applicant or licensee must have an ERA”</p> <p>Should also be specific here and throughout that an EA for a new facility would cover all the requirements of an ERA.</p> <p>There are exceptions allowed to this in the document for a graded approach to these requirements. Need to ensure that this is clear for the ERA as well.</p>	CSA standard states the following: “The ERA, or equivalent risk assessment, can be part of an EA, the EMS, or any other document that contains the required information. All references to an ERA are to be understood as referring to any document that contains the required information.”	Major Comment	Regulatory uncertainty when inconsistent expectations
15.	Purpose P. 1, s. 1.1,	Para. 3, bullet 2: The use of the term EA should be restricted to refer to EA as defined in CEAA 2012. It creates confusion to refer to environmental protection reviews under NSCA as an “EA”.	“EA under the NSCA” should be replaced with “environmental protection assessment” (EPA) under the NSCA	Major Comment	Will result in confusion between CEA requirements and NSCA requirements for industry and the public
16.	p. 1, s. 1.1, 3 rd para.	Stipulates that ERAs are required for both new and existing facilities. In other cases it is required for new and existing facilities and <u>activities</u> .	Need clarification.	<i>Clarification</i>	Inconsistency.



UNRESTRICTED

17.	1.2, Scope, para 3	Clarity is required to confirm that REGDOC-2.9.1 is not intended for transportation of nuclear substances licence applications.	Revise wording to add words in italics as follows: “This document will be used to assess licence applications for proposed new nuclear facilities or activities <i>associated with nuclear facilities</i> , licence applications for existing facilities (renewals and amendments), new ERAs...”	<i>Clarification</i>	
18.	1.2, Scope	Licensed Class 1 facilities have ERAs which are updated at least every 5 years which can be used to support licence renewals and amendment applications.	Explicitly state that an existing valid ERA may be submitted with a licence application even if it has not been created specifically for the licence application.	<i>Clarification</i>	Creating new ERAs when valid ERAs already exist is wasteful of resources.
19.	1.2 Scope	This section must explicitly state that an EA under the NSCA would only be required when a Commission-level decision is needed to authorize the activity and not for changes or requests that are within a licensing basis.	See previous comment 7	Major Comment	See previous comment 7
20.	1.2, scope, Notes bullet 1	Clarification sought for how a licensee should characterize and demonstrate no interaction for activities with no environmental interaction.	Provide additional detail on characterization and demonstration requirements The bullet should be deleted or read: “for facilities or activities with no or insignificant environmental risk or interaction, the CNSC will confirm no environmental review is necessary.”	<i>Clarification</i>	



21.	1.3	<p>G-228, Developing and Using Action Levels will be superseded by CSA N288.8 on Action Levels. N288.8 is still in draft and is expected to be issued late 2016 to early 2017. N288.8 will be relevant once it is approved.</p> <p>There is potential conflict between draft REGDOC 2.9.1 and draft CSA N288.8.</p>	<p>State that once CSA N288.8 is issued, and is included in the facility license and /or the License Condition Handbook, it will provide the method to determine and calculate action levels.</p>	Major Comment	<p>Conflicts exist between draft REGDOC2.9.1 and draft N288.8. Industry needs clear direction on which to follow. To eliminate misalignment of requirements, REGDOC 2.9.1 should defer to N288.8 with respect to Action Levels.</p>
22.	2.0 (Fig 1) and throughout (12-NBP)	<p>Consistently suggest that an ERA is part of an EA. This is contrary to EA theory – planning process before key decisions made vs. risk based on actual emissions / chemicals of concern.</p> <p>There is nothing in previous or existing EA legislation that requires an ERA as part of an EA.</p>	<p>Suggest clarification that EA is a planning tool, and may or may not include an ERA. For a new facility, an EA is appropriate, but without data on emissions / receptors, an ERA may be impossible.</p>	Major Comment	<p>Regulatory uncertainty when inconsistent expectations</p>
23.	2.0 (Fig. 1)	<p>The figure title should be revised to reflect the scope of the REGDOC and does not apply to screening decisions made by CNSC Staff.</p>	<p>Title should be revised to: Environmental protection processes and measures for <u>applicable</u> facilities and activities</p>	Major Comment	



<p>24.</p>	<p>2.1, para. 2 and 4.2.1</p>	<p>New Concepts: The bullet “respect the principles of pollution prevention, precautionary principle, polluter pays, sustainable development and adaptive management”</p> <p>This section introduces a number of new concepts and programs that would need to be demonstrated and may be costly to implement. These concepts and programs go above strict compliance with regulations and therefore should not be mandated by a regulatory body. The opening statement has this as a “shall”.</p> <p>Use of Best Available Technology Economically Achievable (BATEA) “The applicant or licensee shall demonstrate that... their measures taken to protect the environment and the health and safety of persons...recognize that uncertainty exists in science, and therefore prevent unreasonable risk...through the application of the best available technology and techniques economically achievable (BATEA) for hazardous substances”</p> <p>Section 2.1 requires BATEA which is a major policy shift. It is not consistently required by other jurisdictions, so this is a potentially big change.</p> <p>This should only be applicable where significant risk may exist. It’s possible to have high uncertainty with fairly low risk and therefore not need to apply BATEA.</p> <p>Section 4.2.1 recommends the licensees “should” perform “BATEA assessment”. These assessments are not defined. Does the bullet on BATEA assessments require some formal, periodic review?</p>	<p>The ‘shall’ in the first sentence should be ‘should’.</p> <p>The sub-bullet beginning with “respect the principles of...” should be deleted or paragraph starting with “ the applicant” should be deleted</p>	<p>Major Comment</p>	<p>Reputational, as it calls into question whether these principles are being addressed or not.</p>
------------	-------------------------------	--	--	----------------------	---



UNRESTRICTED

25.	Section 2.1	What are CNSC’s current examples of “performance indicators and targets that are based on sound science”? How does the CNSC intend to make sure that these are agreed upon by the licensees? Existing performance measures and targets should be used as much as possible to avoid conflicting with current accepted practice.	Need clarification.	<i>Clarification</i>	
26.	2.1	How will the cost/benefit analysis concept be incorporated into section 2.1? How does CNSC discussion paper DIS 16 01 fit into this discussion?	Cost/benefit analysis concept needs to be incorporated.	Major Comment	Cost, time, and resource implications.
27.	2.2	Title should be: Factors considered by CNSC in licensing decisions		<i>Clarification</i>	
28.	2.4	REGDOCs should not overlap. REGDOC-3.2.2 provides full requirement on Aboriginal Engagement.	Delete this section.	Major Comment	Overlapping REGDOC may lead to different requirements in future years as the document revisions become out of sync leading to confusion for licensees and stakeholders.
29.	2.4 Notes	Bullet 2: it is not clear whether the term EA is used to review to CEAA EAs and/or “EA under the NSCA”.		<i>Clarification</i>	
30.	3. Heading	Heading (and all subsequent headings referring to non-CEAA-specific environmental assessments) and body should be revised to differentiate between “environmental protection processes” (EA-CEAA and EPA) such as the para. 3 reference to “EA process”.	This should be “Environment Protection Assessments ”	<i>Clarification</i>	
31.	3 and 3.2.2	CNSC Staff has indicated verbally that a project on federal lands requiring CNSC <u>Commission</u> approval triggers a S67 responsibility for the CNSC. If a project on federal lands only requires CNSC <u>Staff</u> approval, there is no S67 responsibility for the CNSC. Is the process under an EA under CEAA the same as a section 67 decision process?	This should be explicitly stated in the REGDOC. Provide guidance on where the section 67 decision fits	Major Comment	Will avoid confusion during the early planning/scheduling phase of a project



UNRESTRICTED

32.	Section 3	<p>The distinction between the types of EA's (NSCA vs. CEAA 2012) is not defined clearly.</p> <p>The terminology of EA in terms of a license application for an existing facility is inappropriate – an EA is supposed to be a planning tool – once a facility is in place, it is no longer an EA. Repeat of issue with last version.</p>	Define Clearly	<i>Clarification</i>	
33.	p. 7, s. 3 para.1, also p. 9 para. 6	<p>Statements like “All licence applications are subject to an environmental assessment (EA), commensurate with the scale and complexity of the environmental risks” do not entertain the possibility that no EA is necessary (i.e., where there are no interactions with the environment).</p> <p>Presumes all licence applications require an EA, whereas elsewhere in the document it is clarified that no EA may be required in instances where there is no interaction with the environment.</p>	Consider rewording “All licence applications <u>may be</u> subject to an environmental assessment...”	Major Comment	Regulatory uncertainty
34.	REGDOC (pg. 7, section 3)	<p>Licensees, regulators, and stakeholders can take comfort that ERAs are predictive in nature and thus the level of risk evaluation is equivalent in terms of standards and environmental protection to that of and EA under CEAA.</p>	Continue with this good practice and make a direct statement that an ERA under the NSCA is equivalent in terms of standards and environmental protection to an EA under CEAA	Major Comment	Supports the Licensee and provides the Licensee with regulatory certainty/timeline/requirements under NSCA or CEAA.
35.	3.1, Notes, bullet 2, p. 7 vs. 3.2.2, Note, p. 9	<p>3.1 Notes state that an EA under CEAA may also require an EA under the NSCA while the 3.2.2 Note seems to contradict this.</p>	Clarify requirement.	<i>Clarification</i>	
36.	3.1 Notes	<p>Bullet 2 should be revised. EAs are not on-going. What is on-going is environmental protection oversight.</p>	Change to “all licensed facilities and activities are subject to ongoing environmental protection oversight.	Major Comment	Loss of regulatory certainty and public confusion



37.	Section 3.2	"The assessment is commensurate with the scale and complexity of the environmental risk associated with the nuclear facility or activity." This guidance is vague. An example of CNSC expectation would be useful.	Please provide an example of CNSC's expectation of an ERA based on the scale and complexity.	Clarification	
38.	Section 3.2.2 page 8	For an EA under CEAA, the applicant submits a project description for an EA determination (as outlined in Appendix A). For EA under the NSCA, it is unclear what information on the project is needed within the license application and whether an EA determination will be provided by the CNSC.	Include guidance on what information is required in the license application for EAs under the NSCA in order for CNSC to make EA determinations.	Clarification	
39.	S. 3.2.2, p. 8	The first bullet makes it clear that the section applies to licence applications whereas the second bullet suggests all decisions require an ERA. No changes need to be made if it is made clear earlier in the document that the EA under the NSCA only comes after a determination as to whether any review is necessary.	See comment number 7	Major Comment	See comment number 7
40.	Section 3.2.2 page 10, Documenting the EA findings	"CNSC staff may prepare an EA report..." How does the EA report differ from the EA under the NSCA? Also the term "EA report" is used for an EA under CEAA.	Clarify how the EA report might differ from the EA under the NSCA.	Clarification	
41.	3.2.2 Page 10, 2 nd last paragraph	The draft REGDOC is confusing when it states, "if an EA report is prepared..."	Clarify "if" statement. Change to: "Any EA report prepared will be made available to the public on request".	Clarification	
42.	3.2.2 Page 11, Presenting the EA information to the Commission to support a licensing decision	This section duplicates information found in the CNSC's "Rules of Procedures".	Delete this section.	Major Comment	Overlapping regulatory documents may lead to different requirements in future years as the document revisions become out of sync leading to confusion for licensees and stakeholders.
43.	Section 3 EA process (26-NBP)	Gone from 9 steps to 2 ... have lost any reference to timelines,	Add timelines to steps	Clarification	



UNRESTRICTED

44.	3.2.2. page 9 "Role of applicants ERA"	Statement that the ERA established bounds is misleading or inaccurate. Bounds may be established by provincial or other jurisdictions not using ERAs. Even an ERA says "for a specific set of emission, here is the risk" above or below criteria. Does not set limits – see section 4.1.	Revise to reflect that other federal and provincial requirements typically establish bounds and that an ERA may help inform / confirm that these bounds are appropriate	Major Comment	Major – if ERA is used to establish / replace regulatory limits, it will put us at odds with other federal and provincial legislative requirements.
45.	REGDOC (pg. 8, section 3.2.2)	<p>It states: "The applicant or licensee should complete the ERA and develop their environmental protection measures prior to submitting the licence".</p> <p>Environmental Protection Measures may not be developed prior to submission. This sentence implies that a draft ERA needs to be submitted prior to the licence renewal application for vetting acceptance by the CNSC. In practice, the ERA may not be fully completed and environmental protection measures fully developed prior to licence submission. Thus, this is a timing risk and plan for review needs to be discussed and agreed upon at the pre-application stage.</p>	Need to clarify this discrepancy. A Licensee and scenario specific plan/discussion would be acceptable.	Major Comment	Need clarification for better understanding and further discussion if needed.
46.	p. 9, last para.	The bullet listing of what the process for an EA under the NSCA includes does not suggest that the process is commensurate with the level of risk.	"The CNSC's process for an EA under the NSCA includes, <u>if required...</u> "	<i>Clarification</i>	The lack of clarification suggests that all facilities and activities are subject to every requirement listed (e.g., Class II licensees needing to organize opportunities for Aboriginal participation).



47.	p. 10, para. 5	The statements “Documents being presented to the Commission for a licensing decision are made available to the public on request. Aboriginal groups and the public are provided an opportunity to review the information and to provide their comments at a public hearing.” do not acknowledge the need to maintain confidentiality due to security, IP protection or other reasons.	Need clarification.	<i>Clarification</i>	Sets expectations that will not necessarily be met.
48.	p. 10, para. 8, and p. 11, para. 1	Again, the organization of opportunities for public and Aboriginal participation does not acknowledge that this may not be necessary for all EAs. Also, not all licence applicants are subject to public hearings. Some may be subject to closed sessions.	Need clarification. For example, “The Commission considers the licence application in a public hearing, <u>at their discretion...</u> ”	<i>Clarification</i>	Sets expectations that will not necessarily be met.
49.	4.0 Environmental Protection Measures p. 12, para. 3	“The CNSC’s environmental protection safety and control area (SCA) covers measures that identify, control and monitor all releases of radioactive and hazardous substances”. “All releases” is overboard because what is monitored is based on risk.	Replace with “The CNSC’s environmental protection safety and control area (SCA) covers measures that identify, control and monitor the release of radioactive and hazardous substances that pose a risk to the environment.”	Major Comment	Efforts to meet REGDOC 2.9.1 requirements for contaminants and effluent at levels that are below the risk threshold levels will not result in an improvement in environmental performance.
50.	4.0 Environmental Protection Measures p. 12, para. 4	ERAs identify risk areas; they do not necessarily address or mitigate those risks. Clarify that environmental protection measures are required to address only those aspects that are identified as being a risk.	Remove the word “ERA” from “The applicant’s or licensee’s ERA and environmental protection measures should address all aspects of the CNSC’s environmental protection SCA...”	<i>Clarification</i>	
51.	4	Only need to control releases where necessary. Reword sentence.	“...measures identify and (where necessary) control and monitor....”	<i>Clarification</i>	



UNRESTRICTED

52.	4	The REGDOC doesn't have any information on the release limits and how those will be defined. This was expected per the discussion paper.		Major Comment	There were many comments on the discussion paper with respect to release limits. It was expected that there would be clarification in this document.
53.	4.1 Environmental Risk Assessment	"The applicant or licensee's ERA forms the basis of an EA conducted under CEAA 2012 and under the NSCA." The risk and impact assessment under CEAA 2012 does not often follow N288.6 ERA methodologies.	Replace with "The applicant or licensee's ERA forms the basis of an EA conducted under NSCA and informs the EA conducted under CEAA 2012."	Clarification	
54.	4.1 Para. 3, p. 13	Bullet 4 is incorrect and inconsistent with N288.6– the ERA predicts exposure and effects on valued components. Similarly, the second para. Under the Requirements states "all biota (human and non-human). In both cases biota should be deleted and replaced.	Replace "biota" with "valued ecosystem components"	Clarification	
55.	REGDOC (pg. 14, section 4.1.1)	States that: "The applicant or licensee shall demonstrate that the facility or activity has been designed with mitigation measures (engineering and administrative) to prevent or minimize areas of interaction with the environment as identified by the assessment of the effects (through the ERA)." For an existing facility, these have already been addressed in previous licences unless there is a fundamental design change. Furthermore, the ERA needs to be looked upon as a companion document to other pertinent licence submission documents; it should not be meant to house all the information on detailed design and measures (engineering, maintenance, administrative).	Need to have direct language that stipulates that the ERA is not meant to be the repository for information on detailed design and measures (engineering, maintenance, administrative).	Major Comment	Repetition or duplication of information in other documents submitted as part of the licence application.



UNRESTRICTED

56.	REGDOC (pg. 17, section 4.1.2)	<p>It states: "The updated ERA shall be used to assess the environmental performance of the facility or activity relative to the level of environmental effects identified in the licensing basis. The ERA shall also be used to predict continued future performance and associated environmental effects of the facility or activity."</p> <p>While there may be a significant change in facility or activity, there may not be a significant change in environmental effluent/emissions/impacts to warrant an update to the ERA. This depends on predictions.</p>	Need this clarification in the text that significant change in facility or activity does not necessarily warrant an update to the ERA	Major Comment	Eliminates unnecessary updates to the ERA.
57.	Section 4.1 ERA throughout and Appendix B & C	There is use of EA terminology throughout which is not consistent with N288.6 terms. Examples: local and regional study area, residual effects, likelihood and significance, etc.	<p>Recommend not using concepts required for EAs. As an example, for human receptors, the members of the public should align with requirements of N288.1 which may or may not be located in the regional study area. For non-human biota, the site study area may be sufficient.</p> <p>Align with the requirements under N288.6.</p> <p>See also comment 1</p>	Major Comment	If Appendix B and C is applied to ERAs to support the EA under NSCA. The scope goes beyond the requirements of N288.6 and therefore would increase effort.



UNRESTRICTED

58.	4.1 ERA, p. 13, para. 1	"The ERA and its associated performance predictions serve as the basis for control and monitoring of releases, environmental monitoring, and any supplementary studies." Provincial and Federal Regulatory monitoring requirements have a larger impact on effluent monitoring program than ERA.	Replace with "The ERA and its associated performance predictions, and regulatory monitoring requirements, serve as the basis for control and monitoring of releases, environmental monitoring, and any supplementary studies."	Clarification	
59.	Section 4.1 page 13 and throughout	The term "initial ERA" is confusing as it appears to be referring to both a retrospective ERA (baseline) and a predictive ERA (for a project). It is not clear if the initial ERA is only referring to an ERA for the project (i.e. predictive ERA).	Use terminology in N288.6 such as "retrospective" and "predictive." See comment 1 Conflict between this REGDOC and 288.6	Major Comment	See comment 1
60.	Section 4.1 page 13, para. 2	"Measured at controlled sites" and "statistically defensible level of confidence" - Environmental Monitoring Program should be developed in accordance with the requirements as outlined in CSA N288.4.	Align with the requirements under N288.4 See comment 1 Conflict between this REGDOC and 288.6	Major Comment	The need for controlled sites and statistically defensible level of confidence should be based on data quality objectives as developed for the EMP (consistent with N288.4). The need for this type of sampling plan may increase the complexity of the ERA.
61.	s. 4.1, p. 14, para. 3	The fourth bullet: it is not clear how the precautionary principle is to be applied by licensees. This bullet should be deleted if it is not explained.	Refer to comment on section 2.1	Clarification	
62.	Section 4.1 Guidance para. 2, p.14	Align expectation that interactions only require to be addressed if there is a risk identified. This occurs in other places of the document as well.	The term "interactions" should be replaced with "risk" as there is no need to address interactions if there is no risk.	Major Comment	There should not be an expectation that action is required to address interactions if there is no risk identified.



63.	Section 4.1.1 page 14	<p>For EAs under CEAA, it is recognized that the EA is an early planning tool. Based on the guidance in section 4.1.1, the ERA appears to require detailed design information which may not be available at the licensing stage.</p> <p>In addition, the licensee will need to provide performance and design characteristics of the top- performing similar facilities or activities. This information may not be readily available. This level of project design information has not been historically provided in past EAs/ERAs.</p>	Recommend deleting “The applicant or licensee should identify the performance and design characteristics (with respect to environmental protection) of the top performing similar facilities or activities.”	Major Comment	The need to provide performance and design characteristics of the top-performing similar facilities or activities appears to be a new requirement and it is not clear what information is needed to support this review.
64.	Section 4.1 page 13, 3 rd paragraph; section 4.1.2 page15	Re: “facility- or activity –specific estimates (mean and upper bound)” - If this section refers to a predictive ERA, upper bound estimates should be sufficient for assessment provided the outcome is acceptable.		<i>Clarification</i>	
65.	Fig 3	The EMS is not “within” the EA envelope – the opposite. A facility should have an EMS, and if necessary (legal and other requirements) should conduct an EA, but it is quite acceptable to have an EMS with no EA.	Revise to reflect the appropriate hierarchy.	<i>Clarification</i>	
66.	Section 4.1.1, page 14 bottom & top of page 15	“After completing the design for the facility or activity, the licensee should characterize the likelihood and severity of the residual interactions with the environment and associated potential effects through ad ERA...” – This statement seems out of place as it refers to after the design is completed. Based on earlier statement that the ERA is initiated during the design phase (i.e. before the design is complete), it is not clear if the expectation is that the licensee will need to update the ERA after design is completed and before the facility is built. Is this another predictive ERA for verifying the original predictions based on final design? Is there a requirement to submit this to the CNSC?	“The initial ERA should recommend additional EMP monitoring for follow-up (either to confirm mitigation is effective or to confirm a prediction). The information from the EMP should provide the basis of any future update of the ERA (note: ERAs are updated every 5 years).	Major Comment	Multiple version of the predictive ERA may increase the cost for preparing ERAs for the site.



UNRESTRICTED

67.	4.1.2 Complexity of the environmental risk assessment, p. 15	This entire section does not fully align with CSA N288.6. See comment 1	Eliminate this section and defer to N288.6 instead. If there are requirements that CNSC wants in addition to N288.6, then it would be much clearer and easier to apply if they refer to N288.6, and then have a section that lists additional requirements.	Major Comment	Over time, issues would arise with compliance to CSA N288.6 and this REGDOC they do not completely align.
68.	Section 4.1.2 page 15 first paragraph; page 16	The scope requires consideration of site preparation, construction and operation and decommissioning. This temporal scope is beyond the requirements of N288.6.	Temporal scope should be aligned with the licensing period. Decommissioning phase is so far in the future that it could not be meaningfully assessed in the ERA framework. ERAs tend to be quantitative and therefore sufficient information is not available for assessment.	Major Comment	Increase cost and complexity of the ERA to include all lifecycle phases.
69.	4.1.2 Updating the environmental risk assessment, p. 17, Para. 1	CSA N288.6 already states that the ERA should be reviewed/updated every 5 years or more frequently if major facility changes are proposed. In addition to this, it appears that the CNSC is now asking that the ERA be updated for every license application. They are also stating that it's possible that the "licensee shall update the ERA at a frequency specified by the Commission..."? Consistency and clarity are needed on what the expected frequency for ERA review/update will be. It takes a year to prepare an ERA report for one facility so it is considerable work each time one is updated. See also comment 1	Delete the "licensee shall update the ERA at a frequency specified by the Commission...?"	Major Comment	Over time, issues would arise with compliance to CSA N288.6 and this REGDOC if they do not completely align.



UNRESTRICTED

70.	Section 4.1.2 page 15, 5 th paragraph and page 46, 3 rd paragraph; B.4.1 page 47, 5 th paragraph	“between the environment and the facility” – Effects of the environment on the project or facility is not a requirement in ERAs (and N288.6). This is an EA requirement. See also comment 1	This information is typically provided in the Safety Report and therefore should remove it from the requirements of the ERA.	Major Comment	The scope goes beyond the requirements of N288.6 and therefore would increase effort and cost associated with the ERA.
71.	4.1.2 Figure 2	This figure is “based on CSA N288.6”, but is different from CSA N288.6. See comment 1	Use Figure 5.1 from CSA N288.6 to align.	Major Comment	Over time, issues would arise with compliance to CSA N288.6 and this REGDOC if they do not completely align.
72.	4.1.2 Updating the environmental risk assessment P. 17, Para. 2	“The ERA shall be updated by adding accumulated site knowledge...” We update the entire document following N288.6 procedures using the latest data. The way it is worded makes it sound like the ERA is one document that keeps getting information tacked onto the previous version.	Change to: “The ERA shall be updated with site knowledge derived from:”	<i>Clarification</i>	
73.	4.1.2., p. 16	Site characterization should not be required when an application is for an existing facility where the characterization has been provided previously. Para. 2: hazard quotient screening assessment is not defined in the REGDOC. It should be defined or “hazard quotient” should be deleted.		<i>Clarification</i>	
74.	4.1.2 Figure 3	What is the Periodic Re-assessment box for? Isn't it for the dotted line arrows that feed back to the ERA or is the document referring to something else that needs to be explained?	Provide clarification	<i>Clarification</i>	



UNRESTRICTED

75.	4.1.2	<p>Adequacy Assessments: “The licensee shall assess the adequacy of the effluent monitoring and environmental monitoring for... “</p> <p>“The licensee shall submit the updated ERA and the adequacy assessment of the associated monitoring to the CNSC for technical review.”</p> <p>This is a new requirement that is as yet undefined. Guidance is required on the form of this assessment of the monitoring programs.</p> <p>Under CSA N288.6, the ERA simply identifies risk and informs the effluent and environmental monitoring programs. The assessment of adequacy is not done in the ERA but under the monitoring program.</p> <p>The requirement to submit the adequacy assessment of the effluent monitoring program to CNSC for technical review is beyond the existing requirements under the Radiation Protection Regulations and will create additional burden on licensee and CNSC. Changes to the program to meet Provincial monitoring requirements cannot be delayed by a CNSC technical review.</p>	<p>Move requirements to assess the monitoring programs to Section 4.2 and 4.3.</p> <p>Provide guidance on expectations Delete the requirement to submit the adequacy assessment for the effluent monitoring to CNSC for technical review.</p> <p>Alignment with CSA N288.6 is needed so that industry can comply with one set of requirements. If this is an additional requirement that CNSC wants licensees to comply with in addition to N288.6 requirements, then it should be identified as such and listed out separately.</p>	Major Comment	Increased regulatory burden on industry. The effluent monitoring program includes many requirements to meet provincial regulations. Requiring CNSC technical review on Provincial monitoring requirements is unnecessary and will result in delays in implementing provincially required changes.
76.	REGDOC (pg. 17, section 4.1.2) first paragraph	<p>It states that an ERA shall be updated with the consideration whether there has been “a significant change in science on which the ERA is based”</p> <p>What process and criteria will the CNSC utilize to ensure that the science in question is widely adopted, widely accepted, is proven over time, where the science has been translated into actual practice?</p> <p>Cost, time, and resource implications; differing views on science</p>	Need clarification.	<i>Clarification</i>	



UNRESTRICTED

77.	4.1	2 nd paragraph, pg 13. Should allow an and/or for measurement of baseline information before start or at control sites	"..(measured before the start of any activity and/or measured at control or reference sites)..."	Clarification	
78.	4.1.2	This REGDOC seems to be referring to retrospective ERA, but sometime implies predictive ERA. Should have elements of both where feasible. EA is predictive, but as ERA evolves it should have elements of both (reflect on past data and update predictions).	Need Clarification	Clarification	
79.	4.1.2 Fig 3	Figure references N288.6 but should also point to N288.1 for the HHRA	Need Clarification	Clarification	
80.	4.2	Pg 19, bullet 3: "verify the nature and quantity of releases against compliance criteria (such as limits and action levels)" Action levels are not compliance criteria. The release limits are the compliance criteria. The ALs are an indication of POTENTIAL loss of control events and are set at levels that are EXPECTED TO BE EXCEEDED from time to time.	Remove action levels. Use Release limits only in statement.	Major Comment	Regulatory uncertainty and public confusion
81.	4.2 Effluent and emission control and monitoring, p. 18 para. 1	"Controls on environmental releases are established to provide protection to the environment and to respect the principles of sustainable development, pollution prevention and continuous improvement." Continuous improvement is not an overall goal of the Effluent monitoring program. The goal is to comply with regulations and legal limits, not continually improve	Delete continuous improvement or replace with continuous improvement of higher risk emissions.	Major Comment	Increased burden to continually reduce emission of low risk effluents.



UNRESTRICTED

82.	4.2 Requirements, p. 18, para. 2	<p>“The effluent and emissions control and monitoring shall: Identify and document the infrastructure and activities (such as pipelines or storage) with the potential for significant accidental release to the environment of nuclear and hazardous substances and the barriers (such as primary and secondary containment, and liners) to prevent releases.”</p> <p>Accidental releases are excluded from the Effluent Monitoring Program per N288.5.</p> <p>Similar to the first bullet in this section, this should only be required for significant release points.</p>	<p>. Requirements for effluent monitoring should align with CSA N288.5.</p> <p>Separate emission controls from emissions monitoring to add clarity to the document and only require this for significant release points.</p>	Major Comment	Increased regulatory burden on industry.
83.	Several places in the REGDOC	<p>“Action Levels” are referenced in several places in the REGDOC.</p> <p>The requirement for and application of Action Levels will be described in N288.8 which is expected to be issued in late 2016 or early 2017.</p> <p>See comment 1</p>	State that once CSA N288.8 is issued, and is included in the facility license and /or the License Condition Handbook, it will provide the method to determine and calculate action levels.	Major Comment	Reference to and alignment with future CSA N288.8 is needed so that industry can comply with one set of requirements. If this is an additional requirement that CNSC wants utilities to comply with in addition to N288.8 requirements, then it should be identified as such and listed out separately.
84.	4.2 General	Many of these measures go well beyond the Environment role and into design, operations and engineering.	Provide clarification on how would we demonstrate compliance if requested?	<i>Clarification</i>	
85.	4.2.1	Re: technology/techniques, how will CNSC assess whether licensees are following these criteria? How do we know whether we have done enough?	Provide clarification on what criteria will be used to determine whether licensees are compliant. How would we demonstrate compliance if requested?	<i>Clarification</i>	



UNRESTRICTED

86.	4.2.2 Paragraph 1, p. 20	<p>“As described in CSA N288.5...the ERA provides the technical foundation and structure for identifying the need for, and details of, the effluent and emissions monitoring.”</p> <p>This cannot be found in N288.5.</p>	Rephrase statement if it is not actually taken from N288.5	<i>Clarification</i>	
87.	4.2.2, para. 3, p. 20	<p>“For facilities and activities with releases at quantities too low or too difficult to measure, the licensee may justify the replacement of effluent and emissions monitoring with modelling of releases based on known engineering principles of site-specific process chemistry.”</p> <p>This is a change in wording from the Radiation Protection Regulations and does not incorporate risk.</p>	Replace with “For facilities and activities where the effluent is of low risk or quantities are too low or difficult to measure, monitoring is not required. The licensee may estimate emissions based on site specific process chemistry and engineering principals.”	Major Comment	Alignment with Radiation Protection Regulations so that industry can comply with one set of requirements.
88.	4.2.2 Requirements Paragraph 4, p. 20	<p>The objectives of the Effluent Monitoring Program do not align with CSA N288.5. See comment 1</p>	The objectives of the Effluent Monitoring Program should be those from Section 4 of CSA N288.5.	Major Comment	Alignment with CSA N288.5 is needed so that industry can comply with one set of requirements.
89.	4.2.2	<p>Toxicity Testing: “For effluents released to water frequented by fish, the effluent and emissions monitoring and control shall include fish toxicity testing.....”</p> <p>This goes well beyond the current RPR and CSA N288.5 needs. This goes well beyond any existing federal monitoring requirements and conflicts with provincial monitoring requirements</p> <p>If required, this should only have to implement toxicity testing for effluents with the potential to have significant risk.</p>	Delete requirement for toxicity testing for low risk effluent streams	Major Comment	Increased burden and expense on industry to monitor low risk effluents for toxicity.



UNRESTRICTED

90.	4.2.2, page 21, bullet 1	“to include action levels or other performance indicators “ The draft CSA N288.8 does not require action levels for all contaminants or monitored pathways.	Replace with “to include action levels or other performance indicators where appropriate,”	<i>Clarification</i>	
91.	4.2.2 Guidance	This section does not align with N288.5. See comment 1	This section should be removed and replaced with a reference to N288.5.	Major Comment	Alignment with CSA N288.5 is needed so that industry can comply with one set of requirements.
92.	4.2.2 Guidance, 7 th bullet, p. 21	Guidance includes requirements for training and qualification which is provided in existing REGDOC-2.2.2, Personnel Training	Delete this bullet.	Major Comment	Overlapping REGDOC may lead to different requirements in future years as the document revisions become out of sync leading to confusion for licensees and stakeholders.
93.	4.2.2. p. 22, Para. 5	The discussion on action levels is confusing. It is unclear if AL are only needed for nuclear substances (As per the sentence starting Under the RPR – paragraph 5) or if AL are required for nuclear and hazardous substances.	Clarify that AL are only required for nuclear substances and not to conventional/hazardous substances. State that once CSA N288.8 is issued, and is included in the facility license and /or the License Condition Handbook, it will provide the method to determine and calculate action levels.	<i>Clarification</i>	
94.	4.2 page 18	Second bullet: identify and document the points of release to the environment and the preventive control measures and equipment necessary to regulate and control the release of these nuclear and hazardous substances in the authorized manner This should be similar to the first bullet – i.e. only for significant release points.	Add wording to bullet 2 similar to bullet 1	Major Comment	Increased regulatory burden



95.	4.2.2	CSA N288.1 is for Environment Programs, why is it discussing RP?	Need Clarification	<i>Clarification</i>	
96.	4.2.2 page 22	For all facilities not subject to the <i>Uranium Mines and Mills Regulations</i> , the licensee should develop environmental action levels for the release of nuclear and hazardous substances to the environment. Should include “where required” as we know per the draft N288.8 that it will not be required for everything.	Add “where required”	<i>Clarification</i>	
97.	4.2.2	Performance indicators for operational control, such as action levels, should be established to serve as early indicators of potential loss of control or deviation from expected quality or quantity of releases. Should add “where required per the comment above.	Add “where required”	<i>Clarification</i>	
98.	4.2.2	These action levels should be integrated into the effluent and emission monitoring. Should add “where required per the comment above.	Add “where required”	<i>Clarification</i>	
99.	4.2	“The effluent and emission control and monitoring shall [...] measure, document, and report the quality and quantity of releases to the environment” An estimate is adequate depending on the risk	Replace “measure” with “monitor”	<i>Clarification</i>	
100.	4.3 page 23	2 nd bullet. Organism level effects only need to be considered for Species at Risk (SARs). This should be clear in here.	Need Clarification	<i>Clarification</i>	
101.	4.3 General, p. 23	Is this section describing requirements for the ongoing EMP or for the EMP information required for the license application? If it is the information required for the license application then it is a lot of information and is essentially the entire EMP program.	Provide clarification if these requirements are expected to be contained within an ERA or if they are just describing general requirements for the EMP.	<i>Clarification</i>	



UNRESTRICTED

102.	4.3 p. 23, third black bullet	Need to place bounds for when reporting required on physical stressors	Change to “the intensity of physical stressors and their potential effect on human health and the environment <i>if such potential is predicted by the ERA or required by legislation</i> ”	Clarification	
103.	4.3 Requirements Paragraph 1, p. 23	“The licensee shall use the ERA to identify the need...” Reword to include monitoring that is done where no risk is identified in the ERA but is required due to legislation.	Change to “The licensee shall use the ERA (or legislation) to identify the need for and complexity...”	Clarification	
104.	4.3 Requirements Paragraph 1, Pg. 23 and 4.2.2 Requirements Para 3, Pg 24	These sections describe providing justification if changes are required for the Environmental and Effluent Monitoring Programs. Does this mean that we aren’t meant to make any changes to these programs until the next licence renewal? EMP, there isn’t a requirement to request approval when making changes as it evolves from year to year. The annual EMP report provides information on the changes made and any major upcoming changes.	Remove these paragraphs or rephrase to indicate these are referring to changes to address any changes related to the licence application (i.e. if it’s for a new operation/lifecycle phase, new construction, etc.)	Major Comment	The EMP is an evolving program that may be updated at any time if necessary to address risks, new receptors, etc. There should not be an expectation that it remains unchanged until licence renewal.
105.	4.3 Guidance 8 th bullet, p. 24	Guidance includes requirements for training and qualification which is provided in existing REGDOC-2.2.2, Personnel Training	Delete this bullet.	Major Comment	Overlapping REGDOC may lead to different requirements in future years as the document revisions become out of sync leading to confusion for licensees and stakeholders.
106.	4.3 Guidance, p. 24	N288.4 already outlines requirements for Environmental monitoring programs at Class I nuclear facilities and uranium mines and mills. This section does not fully align with N288.4. See comment 1	This section should be replaced with reference to N288.4.	Major Comment	Alignment with CSA N288.4 is needed so that industry can comply with one set of requirements.



107.	4.3 page 25	“Some examples of biological effects monitoring that may be required depending on the risk posed by the facility are benthos and fish.” Not sure what this example means.		<i>Clarification</i>	
108.	4.3, p. 25, para. 2 and 4	First bullet: this should read “components <u>of</u> air...” Last sentence of para. 4 does not provide examples of monitoring”	Some examples of biological effects monitoring that may be required depending on the risk posed by the facility are benthos and fish” should be replaced by “Some examples of biological effects monitoring that may be required are tissue chemistry, population status, habitat conditions.”	<i>Clarification</i>	
109.	4.3 Guidance Note, p. 25	“Even if the site-specific ERA indicates little potential for measurable levels of stressors or effects in the environment, consideration should be given to the benefit of confirmatory monitoring...” This circumvents the entire purpose of performing an ERA.	Delete this “Note”.	Major Comment	This requirement is not stated in any other standards and offers no improved environmental performance or protection with unnecessary regulatory burden.

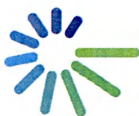


UNRESTRICTED

110.	4.5 Groundwater protection and monitoring, p. 26	General Statement about this section: <i>Inconsistent language between this document and N 288.7</i> <i>See comment 1</i>	Use the same language that is in the CSA N 288.7.	<i>Major Comment</i>	Because this document and N288.7 will become part of the conditions in a licence, it is critical that both documents use consistent language and phrases/clauses so that there is no ambiguity in interpreting the clauses or the intention of each clause. A great amount of time, resources and effort was put into generating N288.7 to be a thorough, thoughtful and useful standard, therefore this REGDOC should concur with the standard and not create differences.
111.	4.5.1 Groundwater protection, p. 26	3 bullets – Prevent, stop, minimize. Use the same language as N288.7 .It is difficult to understand how to apply these actions to the conditions stated in the section and in some situations they are not applicable. The use of “any” is absolute and is not used in N288.7. See comment 1	Use the same language that is in the CSA N 288.7. Delete “any”.	Major Comment	By using the same language, there is consistency and avoids ambiguous or contradictory interpretations. The N288.7 was written to ensure the actions and rationales are clear.



112.	4.5.1 Requirements Paragraph called "Note", p. 27	<p>Discharging certain liquids or slurries to the ground surface is one method to manage excess liquids, i.e. water. The licensee should be allowed to discharge liquids to the surface and thus infiltrate water into the sub-surface as long as the licensee can demonstrate that the filtrate caused no significant environmental impact. Similarly this note should not apply to development or purged water from a monitoring well. If this water will not cause an environmental impact it should be allowed to be discharged to the ground as means of managing development/purged water. This is common industry practice.</p> <p>Will restrict the options to manage slurries or waste water from certain situations.</p> <p>Negative cost impacts to truck and dispose of slurries or waste water if there is no significant environmental impact.</p>	Delete the note	<i>Clarification</i>	
113.	4.5.2 Groundwater Monitoring, p. 27	<p>First two bullets want groundwater quantity to be determined, etc.</p> <p>This is not consistent with CSA N288.7. The standard uses language regarding groundwater quantity in specific cases. Groundwater quantity is important if there is an aquifer that contributes to and is a source of drinking water. If the groundwater end-users and vulnerability assessments determine there is no reasonable potential for the aquifer to be a groundwater drinking water resource, there is no need to complete the actions in the first two bullets.</p> <p>See comment 1</p>	Use the same language that is in the CSA N 288.7, i.e., section 0.2.2 and 0.2.3.	Major Comment	Unnecessary and ambiguous requirements without added value. This section needs to be consistent with the objectives stated in N288.7 for Groundwater Monitoring Programs.



UNRESTRICTED

114.	4.5.2 Groundwater Monitoring, p. 28	Fifth bullet: <i>"confirming that unauthorized changes and releases to groundwater are not occurring ..."</i> It is not clear what <i>"unauthorized changes"</i> means in the context of groundwater monitoring. See comment 1	Use the same language that is in the CSA N 288.7, i.e., section 0.2.2 and 0.2.3.	Major Comment	This section needs to be consistent with the objectives stated in N288.7 for Groundwater Monitoring Programs.
115.	4.5.2 Groundwater Monitoring – Guidance, p. 28	Third bullet: <i>"performance indicators"</i> is not defined and is not consistent with N288.7. See comment 1	Replace <i>"performance indicators"</i> with <i>"evaluation criteria"</i> .	Major Comment	This section needs to be consistent with the Section 3 Definitions and Section 7.2.8 Definition and Establishment of Groundwater Evaluation Criteria as stated in N288.7 for Groundwater Monitoring Programs. N288.7 does not use <i>"performance indicators"</i> ; rather <i>"evaluation criteria"</i> is used and is clearly defined.
116.	4.5.2 guidance, p. 28	Guidance includes requirements for training and qualification which is provided in existing REGDOC-2.2.2, Personnel Training	Delete this bullet.	Major Comment	Overlapping REGDOC may lead to different requirements in future years as the document revisions become out of sync leading to confusion for licensees and stakeholders.



UNRESTRICTED

117.	4.6 Environmental Management System, General, p. 28	<i>The document does not recognize that ISO 14001:2004 has been revised and that to ISO 14001:2015 has been approved by CSA</i> This is a time-sensitive issue because companies registered under ISO 14001:2004 have until September 15, 2018 to transition to ISO 14001:2015. Significant lead time is required to transition due to a large number of added requirements. It is critical to inform licensees whether adoption of the revised standard will be supported by the CNSC, and whether it is acceptable to remain compliant with ISO 14001:2004.	Licensees should be permitted to either transition to ISO 14001:2015 or to remain compliant to ISO14001:2004.	Major Comment	Regulatory certainty
118.	4.6 page 28	EMS is not considered a database and calling an EMS a system is redundant. See proposed wording.	An EMS is a management tool providing the framework that integrates policies, measures and procedures for ensuring organizational commitment to environmental protection and continual improvement by	<i>Clarification</i>	
119.	4.6 page 28	"Identifying and managing environmental risks associated with a facility or activity (the ERA)" ...Remove ERA or add additional methods, as there are various forms of "risk assessment" used to identify environmental aspects of the organizations.	Identifying and managing environmental risks associated with a facility or activity. ¹	<i>Clarification</i>	
120.	4.6.2, p. 29	See comment 1. Inconsistent with ISO 14001	Para. 2, bullet 4: "conduct an annual..." should be deleted and replaced with "conduct at planned intervals..." to be consistent with the referenced clause.	Major Comment	Regulatory certainty



UNRESTRICTED

121.	4.6.2 page 30	<p>The EMS is the integrated set of documented activities (policies, measures and procedures) that provide a framework for action for environmental protection.</p> <p>“action” is not the correct word; rather EMS provides the framework or basis for an effective program.</p>	<p>The EMS is an integrated set of documented activities (policies, measures and procedures) that provide a framework for an effective environmental management program.</p>	<i>Clarification</i>	
122.	4.6.2 Scope of Environmental Management System, Guidance, p. 30	<p>The document overemphasizes the potential value of an ERA in assessing significant environmental aspects by suggesting it be the “core document”. ISO 14001:2015 introduces new requirements for the consideration of risks and opportunities that provide licensees with limited flexibility to decide how risk can be considered in the EMS. Industry values this flexibility as the scope of the OPG EMS is includes facilities that do not require a formal ERA and other risk assessment methods are considered</p> <p>Guidance: To avoid misinterpretation of these concepts, the licensee should review the following differences between key concepts in federal legislation and those in CAN/CSA ISO 14001 [1] and consider them in the scope of their EMS:</p> <p>For Bullets 2, 3 and 4 it is unclear what is expected and what definition to use or how to use it.</p> <p>SEE COMMENT 1</p>	<p>Remove Discussion and refer to ISO 14001</p>	Major Comment	<p>This is a time-sensitive issue because companies registered under ISO 14001:2004 have until September 15, 2018 to transition to ISO 14001:2015. It is critical to inform licensees at the earliest possible time how the CNSC views the additions to ISO14001 regarding risk and opportunities.</p>
123.	4.6.2 top pg. 31 -	<p>Top - pg31. Missing “nuclear” between class I and facilities. Does this apply to transport licenses as well?</p>	Need Clarification	<i>Clarification</i>	



UNRESTRICTED

124.	4.6.2 Pg 30 second last bullet	The role of an ERA in the selection of significant environmental aspects goes well beyond what is required in ISO 14000 and will be difficult to implement. See comment 1	Remove ERA from this section. Assessment of significant aspects should be limited to ISO 14000 requirements.	Major Comment	Regulatory confusion
125.	4.6.3 Other considerations Page 32	Guidance includes requirements for training and qualification which is provided in existing REGDOC-2.2.2, Personnel Training	Delete this bullet.	Major Comment	Overlapping REGDOC may lead to different requirements in future years as the document revisions become out of sync leading to confusion for licensees and stakeholders.
126.	4.6.3, other considerations. Pg 31	This section provides requirements contained in REGDOC 2.10.1	Delete this section	Major Comment	Overlapping REGDOC may lead to different requirements in future years as the document revisions become out of sync leading to confusion for licensees and stakeholders.
127.	A	pg 33 3 rd pt. If project likely to cause sig adverse env effects, but can be mitigated to below acceptable levels, is it still necessary to refer to Governor in Council?	...if the CNSC determines that the project is likely to cause significant adverse environmental effects, once implementation of mitigation measures have been taken into account, then in accordance with section 52(2)...	<i>Clarification</i>	
128.	A	Figure 5. Need definition for CMD.	Need Clarification	<i>Clarification</i>	



UNRESTRICTED

129.	A, page 34	This section refers the user to the operation policy statement for projects on federal lands. However this document does not provide the guidance on which projects the CNSC is required to conduct a review of in accordance with Section 67. CNSC Staff has indicated verbally that a project on federal lands requiring CNSC Commission approval triggers a S67 responsibility for the CNSC	If a project on federal lands only requires CNSC Staff approval, there is no S67 responsibility for the CNSC. This should be explicitly stated in the RegDoc.	Major Comment	Regulatory confusion
130.	A.1, Page 34	Timelines are not provided for CNSC EA Activities for the Sequential EA and Licensing Approach. . We note that CEAA 2012 provides a 365 day timeline, with the possibility of an extension for Environmental Assessments conducted by the Canadian Environmental Assessment Agency. The timeline is for Agency Activities only.	Timelines should be provided to provide licensees with more certainty on the duration of EA approvals	Major Comment	Will provide licensees with more certainty on duration for regulatory approvals.
131.	A.1, p. 35-36	Figure 5: “ER determination” should be replaced with “process determination” and a “neither process required” option should be added to “ER determination”.	Figure 5 should align with Table 1.	Clarification	
132.	A.2 (Step 2)	The document should clarify what is required for an “initial licence application with the minimum information needed to start the EA process” (for the sequential approach). What is the minimum information required?	List of required documents for an “initial licence application”	Clarification	
133.	A.2 (Step 5)	This section describes that EA guidelines may not be required when the EIS and technical studies have already been completed. Are there any other situations where EA guidelines may not be required?	Clarify if the ONLY situation where EA guidelines may not be required is when the EIS and technical studies have already been completed	Clarification	
134.	Sect A.2 step 5	Timeline for EA guidelines – when can we expect to review/receive the guidelines?	Need Clarification	Clarification	
135.	A.2 (Step 6)	Note states that to meet CEAA 2012 requirements the licensee shall conduct an ERA. However, this shouldn’t be a requirement for a new facility, the EA is the first ERA. ERAs are not a specific requirement for CEAA 2012	Remove the note	Major Comment	Confusion with respect to regulatory requirements



UNRESTRICTED

136.	A.2 (Step 7, P.39)	Step 7 (Technical Review of the EIS) Does not state that Federal Authority input is requested during this step; instead FA input is described in Step 8 (EA report). Wanted to confirm if this is indeed the case (makes a difference in scheduling a project)	Need Clarification	<i>Clarification</i>	
137.	A.3	Should state that the bulleted items come from CEAA (19). Is it really appropriate to quote information from CEAA or should the REGDOC just point to CEAA section 19.	The EA of a designated project shall take into account the following factors (as required by CEAA s 19):	<i>Clarification</i>	
138.	A.3	3 rd pt, pg 41. Here it indicates that mitigation is only needed if significant effects are possible. Contradicts statement on previous page.	Need Clarification	<i>Clarification</i>	
139.	Appendix A page 35, figure 5	Figure 5 should include some timelines to provide the proponent/applicant some certainty in the process.	Include timelines	<i>Clarification</i>	
140.	Appendix A.3.9 page 44 last paragraph	Suggests that the applicant apply methodology described in N288.6 for the assessment of effects of the environment on the project.	Delete last paragraph	<i>Clarification</i>	
141.	A3.2 page 41	Alternative means for carrying out the project. The second paragraph is confusing. Suggest re-wording this to include more exact criteria (e.g. dictate what criteria should be used to assess the alternative means). Also, the subtle choice of what is acceptable is not necessarily clear.	Need Clarification	<i>Clarification</i>	
142.	A	This section provides detailed guidance on what is required for conduct of an EA under CEAA. However, there is no guidance or timelines for conduct of a determination under Section 67 or an EA under the NSCA. Need to understand what information is required by the CNSC to make these decisions.	Add information for conduct of a section 67 determination and conduct of an EA under the NSCA.	Major Comment	Unclear regulatory requirements



UNRESTRICTED

143.	B.1	This ignores provincial guidance and this should provide that atmospheric details should align without the requirements of other jurisdictions, where possible.		Major Comment	
144.	App B2 page 46	Re: study design should be fully described. This level of detail is typically not included in an ERA.	Recommend that reference to sampling plans, and analytical results are sufficient. This level of detail is not typically brought into an ERA as EMP has the detail plans and results.	Clarification	
145.	B3 - Para 5 Last sentence	<i>"The applicant... and their critical habitats, if identified."</i> Add the if identified at the end.	Need Clarification	Clarification	
146.	B.4	This section goes beyond previous baseline programs completed to support any of our currently approved EPAs.		Major Comment	
147.	App B5, page 48, 5 th paragraph	Need to describe existing soil quality for <i>all</i> study areas. Typically ERAs will focus on the immediate site study area where the facility will likely to influence the soil quality and the worst-case concentrations are likely to exist.	Delete word "all".	Clarification	
148.	B.5	Para. 2: "species of conservation concern..." does not align with the definitions in <i>Species at Risk Act</i> . It is unclear how "reasonable potential to occur" is defined with regard to the likelihood that a species may or may not be present. Para. 3: what is the process if critical habitat has not yet been identified?	Align with the definitions in <i>Species at Risk Act</i> .	Clarification	
149.	B5 - Para 3 Last sentence	Remove the last part of the last sentence "... and physical barriers to movement that exist or will exist as a result of the facility or activity." This should go under C5	Need Clarification	Clarification	



UNRESTRICTED

150.	B.7	These details are completed in the CEAA-EA but are not part of the scope when characterizing the baseline environment (population health profiles).		Major Comment	
151.	Appendix C. through out	"including postulated accident and malfunction scenario" – Malfunctions and Accidents goes beyond the scope of an ERA as defined under N288.6	CNSC should rely on the Safety Report to provide this information.	Major Comment	The scope goes beyond the requirements of N288.6 and therefore would increase effort and cost associated with the ERA.
152.	C	This appendix appears to be the "effects assessment" of the CEAA-EA and not an ERA as described in CSA N288.6.	Modify title to reflect content	Major Comment	Regulatory certainty
153.	C.1	This ignores provincial guidance and this should provide that atmospheric details should align without the requirements of other jurisdictions, where possible. Licensees must comply with provincial standards and the discussion here is beyond the scope of required for baseline studies.		Major Comment	
154.	C.3	A number of potential effects in this section are outside the scope of CSA N288.6 (e.g. wetlands, infilling and fish habitat, effects on blasting).		Major Comment	
155.	Appendix C.8, Table on page 53	If C.8. is for EA under CEAA these requirements are fine however if this section is for an ERA these requirements go beyond CSA N288.6.	Change in line with industry concern.	Major Comment	The scope goes beyond the requirements of N288.6 and therefore would increase effort and cost associated with the ERA.
156.	A1, Last bullet	The statement "significant time" is unclear.	Please define "significant time"	Clarification	
157.	Appendix B and C	The titles seem to be incorrect or misleading. Should they read "for an Environmental Assessment" instead of "Environmental Risk Assessment"? Certainly the content and structure align with an EA under CEA, not an ERA.	Change Appendix B and C titles to read "Environmental Assessment" instead of "Environmental Risk Assessment"	Major Comment	The structure of these Appendices does not align with those of an ERA. This content aligns with EAs. Either the titles are incorrect or there is a significant change in the expectation/definition for ERAs.



UNRESTRICTED

158.	Section 3.2, Appendix B and C	<p>Several of the requirements for an ERA in Draft REGDOC-2.9.1 appear to be requirements for an EA under CEAA, and are usually not considered in an ERA, nor are they a requirement in CSA N288.6. For example, consideration of accidents and malfunctions, provisions for monitoring design-based accidents and severe accidents, occurrence of weather phenomena, geotechnical properties of the site, community health profiles, Aboriginal diet when First Nation people are not a critical group, reduction in wildlife productivity, all life cycle stages including decommissioning, etc.</p> <p>As described in the Draft REGDOC-2.9.1 there does not appear to be much difference between an EA under CEA and an ERA.</p>	A table showing what is in an EA Under CEA and what is in an ERA would be useful.	Major Comment	If Appendices B and C are applied to ERAs to support the EA under NSCA, the scope goes beyond the requirements of N288.6 and therefore would increase effort and cost.
159.	Appendix?	CSA N288.6 has a very clear suggested Table of Contents for an ERA. Industry has difficulty envisioning exactly what the REGDOC is asking for in their requirements for an ERA. Ideally it would be the same as N288.6, however, if it is not, can they include in the Appendix of an example table of contents with descriptions for each section similar to N288.6 Annex A?	If the CNSC expects the ERA to contain anything different than what is required by CSA N288.6, then please provide an Appendix with an example table of contents for an ERA, with descriptions under each section, similar to what is provided in N288.6 Annex A.	Major Comment	This would be a useful aid in clarifying exactly what the CNSC requires in an ERA, where there may be additional requirements than those in CSA N288.6, and what the CNSC expects the ERA to look like.
160.	Glossary – Pg 58	The definition of environmental effect is too long, gets into details which is not necessary to the definition and wouldn't apply in most of the ways it's be used throughout the document.	Use definition in previous version of REGDOC	<i>Clarification</i>	



UNRESTRICTED

161.	Glossary	Provide an equivalent definition in the Glossary of EA under the CEAA 2012 as the definition of an EA under NSCA	EA under CEAA: A review by CNSC staff of information used to support the Commission's determination on whether the applicant or licensee will make adequate provisions for the protection of the environment and the health and safety of persons while carrying on a licensed activity in respect to a Designate Project as defined under CEAA.	<i>Clarification</i>	
162.	Glossary pg. 59	<p>Environmental Management System (EMS) <i>(système de gestion de l'environnement [SGE])</i></p> <p>The part of an organization's management system used to develop and implement its environmental policy and manage its environmental aspects. An EMS consists of policies, measures and procedures forming an integrated set of documented activities to provide a framework for action for environmental protection.</p>	...to provide a framework for an effective environmental management program.	<i>Clarification</i>	
163.	Glossary	An evaluation of the potential significant short-term and long-term adverse environmental effects of a project on the surrounding environment.	<p>Environmental effects may be insignificant or positive. Suggest the following:</p> <p>An evaluation of the potential short-term and long-term environmental effects of a project on the surrounding environment.</p>	<i>Clarification</i>	

